DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
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COPY

January 27, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-28

James R. Hill, Sr., Owner
Kenai Custom Seafoods
50590 Patrick Lane
Kenai, Alaska 99611

WARNING LETTER

Dear Mr. Hill:

We inspected your firm located at 50590 Patrick Lane, Kenai, Alaska, on July 22, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 – Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to James R. Hill, Jr., General Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your hot smoked salmon product to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazard(s) reasonably likely to occur, in order to comply with 21 CFR 123.6(c)(1). Specifically, your firm's smoked fish HACCP plan, which you use for hot smoked salmon (vacuum packaged), does not list *Clostridium botulinum* (C. bot.) as a potential food safety hazard. The seafood HACCP regulation, under 21 CFR 123.16, requires you to have a plan for controlling the potential food safety hazard associated with the formation of toxin by C. bot. in the processing of smoked fish.

2. You must have a HACCP plan that lists all of the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for smoked fish lists 3.5% water phase salt (WPS) as the critical limit that must be met at the brining critical control point (CCP). However, it does not appear

that you determine the actual WPS level in the product on a lot-by-lot basis. A 3.5% WPS level is the desired level for smoked fish without added nitrite. A WPS level of 3.0% is the desired level in smoked fish where there is also 100 to 220 ppm of added nitrite in the product to limit the growth of pathogenic bacteria. Although your smoked fish HACCP plan requires a sodium nitrite level of 100 to 200 ppm in the finished product, our FDA laboratory found an average of 67 ppm nitrite in the sample (ten subsamples) of hot smoked salmon that we collected from you on July 22, 1999.

3. You must have a HACCP plan that lists monitoring procedures for each CCP, in order to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for smoked fish does not consistently address the monitoring steps (what, how, frequency, and who) for each CCP in an adequate manner. For example, your HACCP plan lists a review of the daily brining record and the annual laboratory tests results for the WPS level in smoked fish as the assurance that the critical limit of 3.5% WPS in the finished product is met at all other times. Also, the planned annual laboratory test for WPS in the smoked fish represents an inadequate frequency for the occurrence for this purpose. Your firm had no analytical test(s) documentation on hand to show our investigator, as evidence that the WPS level in the smoked salmon is at least 3.5%. Also, although the average WPS level in the hot smoked salmon sample FDA collected from you on July 22, 1999, was above 3.5%, four (4) of the ten (10) subsamples that we tested had a WPS level below 3.5%. Similarly, at the CCP identified as "label/packaging," the HACCP plan does not state specifically what is to be monitored and how the monitoring is to be done to assure that the product is consistently stored at below the identified critical limit of 38 degrees, or is frozen.

4. The inclusion of planned corrective actions in your HACCP plan is optional. Since you have chosen to include them in your HACCP plan, the corrective actions you describe in each case must be appropriate, in order to comply with 21 CFR 123.7(b). Specifically, you identified increasing the salinity and adjusting the time/temperature for the brining CCP as corrective actions when the critical limit for WPS is not met. However, you have not identified other possible corrective actions (e.g. measuring the thickness of the fillets, adjusting nitrite levels) when the critical limit for WPS is not met.

5. You must adequately monitor specific sanitation conditions and practices during processing in order to comply with 21 CFR 123.11(b). However, your firm did not monitor for prevention of cross-contamination from insanitary objects to food. For example, we observed the storage of raw (unprocessed) and cooked (ready-to-eat) product together in the same cooler with no physical separation.

During the previous inspection, on July 20, 1998, you were notified of deficiencies similar to those described in this letter. During the inspection, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in one year's time your firm has not adequately corrected these deficiencies or developed fully adequate HACCP plans. We understand that your firm has promised to make corrections by November 1, 1999, to deficiencies noted by our investigator during the latest inspection.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen.
District Director

Enclosures:
Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
ADEC